REMARKS/ARGUMENTS

At the outset, Applicants would like to thank the Examiner for taking the time to participate in a telephonic interview with Applicants' representatives on March 2, 2006. Applicants believe that the issues discussed during the interview have helped Applicants to understand more clearly the concerns of the Patent Office and to prepare a response that best addresses the outstanding issues.

Upon entry of the present amendment, claims 1, 3-8 and 10-27 are pending in the application and presented for examination. Claims 2 and 9 are canceled without prejudice to renewal in a continuation application. Claims 3-8, 10-24 and 26 are original and unchanged from filing. Claims 1, 25 and 27 are currently amended. More particularly, claims 1, 25 and 27 are amended to set forth one particular embodiment of the invention in which the core tablet does not substantially contain a hydrogel-forming polymer. Support for this amendment is found in the application as originally filed. For example, the specification describes on page 17, line 33, bridging to page 34, line 1, that a hydrogel-forming polymer is considered to be an optional ingredient for the core tablet. Moreover, in Examples 1-4 and 6-9, the formulations *do not* contain a hydrogel-forming polymer in the core tablet. In view of the above, Applicants submit that no new matter is present in this or any other portion of the present amendment. Reconsideration of the application is respectfully requested.

I. REJECTION UNDER 35 U.S.C §102(b)

The Examiner has rejected claims 1, 3-8, 10-19, 21-25 and 27 under 35 U.S.C. §102(b) as allegedly being anticipated by Nakashima *et al.* (EP 0 661 045). The Examiner alleges that that Nakashima *et al.* describe a compression molded formulation comprising i)a core that contains a drug along with solubilizers, and ii) a coating layer that contains a hydrogel formulation of a hydrophilic base and hydrogel-forming polymers as is presently claimed. To the extent that the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

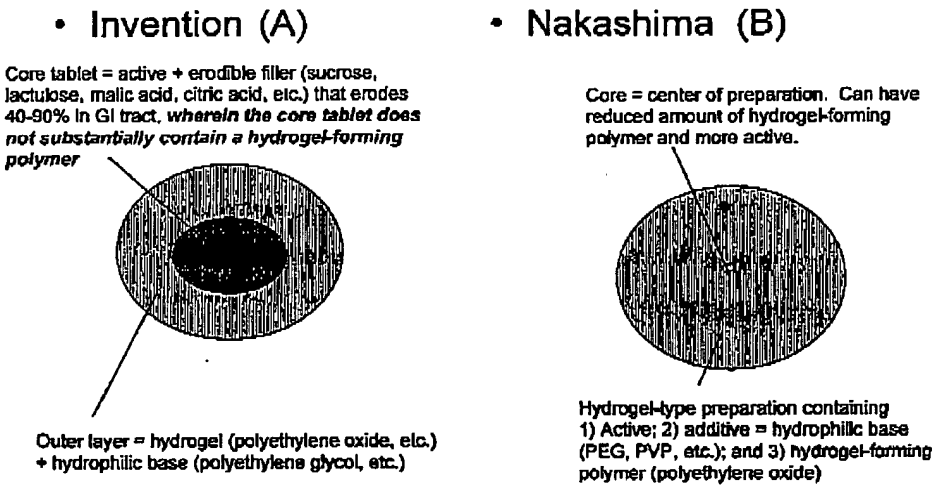
Applicants' invention is for a timed-release formulation, that is a tablet having at least *two distinct layers* each comprising a different formulation. The two distinct layers of the inventive formulation are: 1) a core tablet that has a drug and a freely erodible filler, wherein the core tablet erodes approximately 40% to approximately 90% in the digestive tract of the subject; and 2) an outer layer having a hydrogel-forming polymer substance, and a hydrophilic base, and optionally containing a drug. As stated above, in an earnest effort to advance prosecution of the present application, Applicants have now amended the base claim to recite more particularly, a certain preferred feature of the invention wherein the core-tablet layer of the of the multi-layered time-release formulation ***does not*** substantially contain a hydrogel polymer.

In clear contrast, the sustained-release tablet of Nakashima *et al.* is a single-layered formulation. Applicants respectfully assert that contrary to the Examiner's allegation, the sustained release tablet of Nakashima *et al.* ***does not*** have two distinct formulation layers of a core tablet and a separate coating layer. Rather, as stated above, the sustained release formulation of Nakashima *et al.* is a tablet that contains a *single-layer*, *i.e.*, a homogeneous formulation which comprises a i) a drug, ii) an additive providing for the penetration of water in to the core of the preparation, ***and iii) a hydrogel-forming polymer.*** Applicants respectfully note that Nakashima use of the phrase "into the core of the preparation" or "preparation core" in the description of the single-layered sustained-release tablet is simply to refer to a location within the tablet, *i.e.*, near the middle of the tablet. ***Thus, the "core" region of the tablet of Nakashima does not contain different formulation ingredients than the rest of the tablet.*** As stated above, the sustained release tablet of Nakashima *et al.* is a ***homogenous, single-layered*** formulation comprising i) a drug, ii) an additive providing for the penetration of water in to the core of the preparation, ***and iii) a hydrogel-forming polymer.***

For the Examiner's convenience, a pictorial representation of the inventive tablet (A) and that of Nakashima (B), that clearly shows the differences in the two formulations is presented in Figure 1 below. In particular, Applicants point out that as set forth in the present amendment, the core tablet in the inventive formulation ***does not*** substantially contain a hydrogel polymer. This is in clear contrast to the invention to Nakashima *et al.*, which is for a

homogenous tablet comprising i) an active agent; ii) an additive, *e.g.*, a hydrophilic base; ***and iii) a hydrogel forming polymer.***

FIGURE 1



In order to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently (*Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995). Applicants respectfully assert that Nakashima *et al.* simply do not teach or suggest a ***multi-layered*** sustained release tablet having core tablet that ***does not*** substantially contain a hydrogel polymer as is taught and claimed by Applicants. Therefore, Applicants submit that Nakashima *et al.* do not anticipate or render obvious the claimed invention, and respectfully request that the rejection of claims 1, 3-8, 10-19, 21-25 and 27 be withdrawn.

II. REJECTION UNDER 35 U.S.C §103(a)

Claims 20 and 26 are drawn to a specific embodiment of the invention in which the inventive tablet formulation comprises the benzazepeine drug, *i.e.*, 4'-[(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide. These claims stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Nakashima *et al.* in view of

Taniguchi *et al.* (EP 0 709 386; hereinafter "Taniguchi *et al.*"). To the extent that the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants respectfully assert that the dependent claims 20 and 26, which are dependent on independent claims 1 and 25, respectively, are not obvious over the combined disclosures of Nakashima *et al.* and Taniguchi *et al.* because the independent claims, *e.g.*, claims 1 and 25 are not obvious over the disclosures of Nakashima *et al.* and Taniguichi *et al.*, alone or combined. In particular, Applicants respectfully assert that Nakashima *et al.* do not teach or suggest Applicants' claimed feature of a multi-layered time-release composition comprising a core tablet and an outer layer, in which the core tablet ***does not substantially contain a hydrogel polymer***.

This deficiency in the disclosure of Nakashima *et al.* is not supplemented by the disclosure of Taniguchi *et al.* The invention to Taniguchi *et al.* is for novel benzazepeine compounds and pharmaceutical compositions thereof. Taniguchi *et al.* disclose a list of general pharmaceutical ingredients that can used to formulate a tablet composition comprising the novel benzazepeine compounds (*see*, page 27, lines 30-37). However, Applicants assert that there is no teaching or suggestion in Taniguchi *et al.* for a multi-layered timed release tablet having a core tablet that ***does not substantially contain a hydrogel polymer***. In view of the above, Applicants respectfully assert that the combined disclosures of Nakashima *et al.* and Taniguchi *et al.* do not teach or suggest all of the claim limitations set forth in the pending independent claims, *i.e.*, 1, 25 and 27. Therefore the independent claims 1, 25 and 27 and any claims dependent therefrom, *e.g.*, 20 and 26, also are not obvious over Nakashima *et al.* in view of Taniguchi *et al.* As such, Applicants respectfully request that the rejection of claim 20 and 26 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

Joseph R. Snyder
Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300

JS:sc
60711464 v1